DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2014

Integra LifeSciences Corporation
Ms. Ruthanne Vendy
Regulatory Affairs Manager
589 Davies Drive
York, PA 17402

Re: K142414
Trade/Device Name: Miltex® N-Tralig® Intraligamentary Syringe
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: September 30, 2014
Received: October 2, 2014

Dear Ms. Vendy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K142414**

Device Name: Integra® Miltex® N-Tralig® Intraligamentary Syringe

Indications for Use:

Integra® Miltex® N-Tralig® Intraligamentary Syringe is indicated to be used in conjunction with anesthetic needles and cartridges for injection of anesthetic into the periodontal ligament.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter-Use_ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K142414

510(k) Summary

Submitted by:	Integra York PA, Inc. 589 Davies Drive York, PA 17402 USA
Contact Person:	Ruthanne Vendy Regulatory Affairs Manager Integra York PA, Inc. 589 Davies Drive, York, PA 17402 USA Phone: (717) 757-7974
Date Prepared:	September 30, 2014
Device Trade Name:	Integra® Miltex® N-Tralig® Intraligamentary Syringe
Brands:	Miltex®
Device Common Name:	Intraligamentary Syringe
Classification Name:	Syringe, Cartridge
Class:	Class II
Product Code:	EJI
CFR Classification:	21 CFR 872.6770
Predicate Device:	Intralig Intraligamentary Syringe (K823536) This predicate device has not been subject to a design-related recall.

Device Description:

The Integra® Miltex® N-Tralig® Intraligamentary Syringe is a cartridge syringe intended to inject anesthetic agents into the intraligamentary space (i.e., periodontal ligament). The device consists of a stainless steel syringe body into which a disposable, previously filled, glass carpule (a cylindrical cartridge) containing anesthetic is placed. After attaching a needle to the barrel cap, the device is used to administer an injection to the patient.

The Integra® Miltex® N-Tralig® Intraligamentary Syringe delivers 0.2cc of anesthetic with each ratchet. The ratchet action of the syringe allows for the slow infiltration of anesthetic during the Periodontal Ligament Injection (PDL injection) to help minimize patient discomfort. The 30º adapter helps provide a better angle with difficult-to-reach injections. The syringe comes with a solid barrel and a window barrel.

Indications for Use:

Integra® Miltex® N-Tralig® Intraligamentary Syringe is indicated to be used in conjunction with anesthetic needles and cartridges for injection of anesthetic into the periodontal ligament.

Predicate Device Comparison:

The predicate device is the Intralig Intraligamentary Syringe (K823536). The below table provides a characteristic comparison of the N-Tralig compared to the predicate Intralig.

Characteristic	New N-Tralig	K823536 Intralig	Comparison
Intended Use	Dental syringe used to deliver anesthetic.	Dental syringe used to deliver anesthetic.	Same
Indications for Use	Indicated to be used in conjunction with anesthetic needles and cartridges for injection of anesthetic into the periodontal ligament.	Indicated to be used in conjunction with anesthetic needles and cartridges for injection of anesthetic into the periodontal ligament.	Same
FDA Procode	76EJI	76EJI	Same
Operation	Injects a measured dose of 0.2 cc of anesthesia with each squeeze of the injection trigger	Injects a measured dose of 0.2 cc of anesthesia with each squeeze of the injection trigger	Same
Cartridge Compatibility	Designed for use with standard anesthetic cartridge	Designed for use with standard anesthetic cartridge	Same
Syringe type	Intraligamentary	Intraligamentary	Same
Anatomical use	Oral cavity	Oral cavity	Same
Sterility	Supplied non-sterile	Supplied non-sterile	Same
Ratcheting	single ratchet increment	multiple ratchet increments	One actuation per trigger pull
Syringe Body	Stainless steel	Chrome-plated brass	Material change

Characteristic	New N-Tralig	K823536 Intralig	Comparison
Ball Bearing	Resin	Stainless steel	Material change
Advancement Block Spring	Located in rear of advancement block	Located in front of advancement block	Location of advancement block spring
Trigger Handle	Concave	Convex	Trigger profile
Cleaning Method for this Device	Yes	N/A	Validated process by independent testing lab
Sterilization Method for this Device	Yes	N/A	Validated process by independent testing lab

There are no significant differences in technology, intended use, or design between the subject devices and the predicates selected.

Performance Standards:

One standard has been promulgated under Section 514 of the Food, Drug and Cosmetic Act for cartridge syringes: *ISO 7405 Second edition 2008-12-15, dentistry - evaluation of biocompatibility of medical devices used in dentistry* as published in the Federal Register (Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 034; 01/30/2014).

The complete list of standards used to evaluate the Integra® Miltex® N-Tralig® Intraligamentary Syringe are as follows:

- AAMI TIR12:2010 – *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*
- AAMI TIR30:2011 – *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
- ANSI/AAMI/ISO 17665-1:2006/(R)2013 (EN ISO 17665-1:2006) – *Sterilization of health care products – Moist heat - Requirements for the development, validation and routine control of sterilization process for medical devices* (FDA 14-261)
- ANSI/AAMI ST79:2010/A1:2010/A2:2011/A3:2012/A4:2013 – *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (FDA 14-439)
- ANSI/AAMI ST81:2004/(R)2010 – *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices* (FDA 14-295)

- ISO 17664:2004 – *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*
- ISO 14971 - *Medical devices - Application of risk management to medical devices* (FDA 5-40)
- ISO 7153-1 – *Surgical instruments -- Metallic materials -- Part 1: Stainless steel* (FDA 8-344)
- ISO 7405 - *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]* (FDA 4-212)

Non-Clinical Testing Performed	Results
Manual Cleaning Validation	**Pass**
Pulse pre-vacuum sterilization validation at 132°C for 4 minutes	**Pass**
Pulse pre-vacuum sterilization validation at 134°C for 3 minutes	**Pass**
Gravity Displacement Steam Sterilization Validation at 132°C for 15 minutes	**Pass**

No biocompatibility testing was performed on the proposed devices as 420, 303, and 301 stainless steels are recognized as suitable stainless steels for surgical instruments, parts, and assemblies per ISO 7153-1. Stainless steel has a long history of safe and effective use, and has been used in other medical devices that have been cleared by the FDA.

Conclusions drawn from Non-Clinical Data:

All necessary testing has been performed on the Integra® Miltex® N-Tralig® Intraligamentary Syringe and the results support the conclusion that the subject devices are substantially equivalent to the legally marketed predicate devices based on intended use, materials, technology, and design and as such, do not raise any concerns of safety or effectiveness.